



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

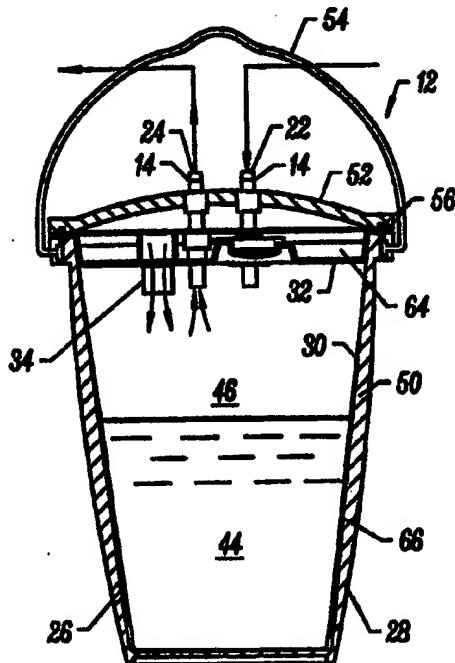
(51) International Patent Classification 6 : <b>A61M 1/00</b>	<b>A1</b>	(11) International Publication Number: <b>WO 98/55164</b>
		(43) International Publication Date: 10 December 1998 (10.12.98)

(21) International Application Number: <b>PCT/US98/11239</b>	(81) Designated States: DE, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: 1 June 1998 (01.06.98)	
(30) Priority Data: 08/868,429 3 June 1997 (03.06.97) US	Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(71) Applicant: FEMRX, INC. [US/US]; 1221 Innsbruck Drive, Sunnyvale, CA 94089 (US).	
(72) Inventors: CHRISTIAN, Jeffrey, J.; 608 Curie Drive, San Jose, CA 95123 (US). DILLOW, David, Curtis; 22851 Longdown Road, Cupertino, CA 95014 (US).	
(74) Agents: BARRISH, Mark, D. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).	

(54) Title: METHOD AND APPARATUS FOR COLLECTING SURGICAL FLUIDS

## (57) Abstract

Surgical fluid collection devices, systems (10), and methods allow individual containers (12) to be coupled in series using a single inflow port (22) with a single outflow port (24) on each container. Surgical fluid are sealed within a disposable liner (26) in each container. In most embodiments, a one-way valve (34) of the liner seals surgical fluid within the liner to prevent spillage to a surrounding vacuum chamber (53) into the interior (46) of the liner to equalize pressure across the liner. This arrangement allows the use of flexible, inexpensive liners with large interior volumes without having to resort to complex pressure equalizing arrangements. A sterilized polymer receptacle (28) is also provided which can withstand the large pressure forces associated with large fluid collection volumes.



***FOR THE PURPOSES OF INFORMATION ONLY***

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroun	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## METHOD AND APPARATUS FOR COLLECTING SURGICAL FLUIDS

5

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

10 The present invention generally relates to medical procedures and devices, and in particular, provides devices, systems, and methods for collecting surgical fluids during minimally invasive electrosurgery and other procedures.

15 Electrocautery has been in use for many years as a general surgical tool, particularly for procedures such as transcervical fibroid removal. In a typical fibroid removal, the uterus is flooded under sufficient fluid pressure to separate the walls of the uterus and render the surgical site suitable for observation. This procedure is generally 20 described as uterine cavity distension. During flooding, an electrocautery surgical tool is positioned within the uterus through the cervix. Electrical current at high voltage settings is transmitted from a cutting surface of the surgical instrument to the surgical site. The electrosurgical device 25 may be either monopolar or bipolar, and the distension fluid may be nonconductive or conductive.

30 The electrical current is concentrated at the cutting surface. Heat generated from the resistance of tissue to the flow of electrical current is high enough to vaporize cells near the cutting surface. Thus, a cut is made with little physical resistance to the cutting motion, and heat from the cut cauterizes small blood vessels, helping to maintain visibility and control.

35 Traditionally, electrosurgical resection of large quantities of tissue has required intermediate flushing of the internal surgical site to remove the severed tissue and electrosurgical debris. While such intermittent flushing can restore image quality, it greatly lengthens the time required

for complete removal of the targeted endometrial tissues during fibroid removal.

More recently, continuous tissue removal methods and devices have been developed which greatly increase the speed of electrosurgical resection. In particular, resectors have been developed which include morcellators to fragment and remove the severed tissues during resection. Additionally, brute electrosurgical vaporization is now used to remove tissues, while a continuous flow of fluid over the surgical site from the direction of the viewing scope maintains image quality. Each of these new, improved procedures involves a significant increase in total fluid volume, as compared to the intermittent flushing of traditional electrosurgery.

A variety of additional surgical procedures have also been developed using large volumes of fluid, together with laser vaporization, microwave heating (often using a cooled fluid), heated and/or cooled fluids for direct tissue ablation, and the like. Hence, a wide variety of therapies, both minimally invasive and traditional, now make use of large volumes of surgical fluids. The collection and disposal of these large volumes of surgical fluid have become increasingly problematic.

A variety of fluid collection devices are currently available. Unfortunately, existing surgical fluid collection systems were often designed with a small container size, as this was generally sufficient for intermittent flushing. In light of the increasing awareness of the dangers posed by blood and other surgical debris, these known small devices have been modified to include disposable liners.

Known lined collection systems have two primary disadvantages. First, a vacuum within the container often draws the fluids into the liner from the surgical site, and known container structures would often collapse under the pressure load if they were resized for modern fluid volumes. In other words, simply increasing the size of existing liners to accommodate increased quantities of surgical fluid can result in large pressure loads across the liner and/or the

surrounding vacuum chamber structure, requiring unwieldy and expensive structures.

5 The second major disadvantage of existing surgical fluid collection systems is that a complex arrangement of tubing is often required to accommodate the numerous small containers and disposable liners. This complexity increases the set-up and break-down time, increases the likelihood of an error during set-up, and greatly increases the probability that contaminated surgical fluids will spill during detachment 10 and removal of the liners.

In light of the above, it would be desirable to provide improved surgical fluid collection devices and methods. It would be particularly advantageous if such improved devices and methods could accommodate the large 15 volumes of surgical fluids which are a by-product of many of the new minimally invasive surgical procedures. It would be especially desirable if such improved devices and methods included a simplified connection arrangement, and facilitated the safe disposal of surgical fluids with minimum risk to the 20 attending medical personnel.

## 2. Description of the Background Art

U.S. Patent No. 4,516,973 describes a one piece disposable collection bag having a rigid cover. U.S. Patent 25 No. 4,675,010 describes a thoracic drainage collection system and method which makes use of a flexible disposable collection bag. U.S. Patent No. 5,470,324 describes a non-refluxing suction canister system.

30 U.S. Patent No. 5,279,602 describes a suction drainage infection control system, while U.S. Patent No. 5,437,836 describes a method of, and container for, treating waste liquid containing body fluid. U.S. Patent Nos. 5,234,419 and 5,185,007 describes suction drainage infection control systems.

35 U.S. Patent Nos. 4,419,093, 4,321,922 and 3,745,999 describe methods of receiving and disposing of fluids from the body, and related devices. U.S. Patent No. 5,112,323 describes a wound evacuator. U.S. Patent Nos. 4,930,997,

4,798,578, 4,795,448, 4,775,360, 4,522,623, 4,346,711, 4,060,107, 3,845,765, 3,704,709, and 3,699,815 are also relevant.

5

#### SUMMARY OF THE INVENTION

The present invention provides surgical fluid collection devices, systems, and methods which are particularly well suited for collection of large volumes of surgical fluids. A simplified collection system allows individual containers to be coupled in series using a single inflow port and a single outflow port on each container. The containers typically include a disposable liner within a vacuum chamber of a rigid receptacle. A one-way valve of the liner prevents the fluid from spilling to the surrounding vacuum chamber, and also admits air from the surrounding vacuum chamber into the interior of the liner to equalize pressure across the liner when a vacuum is drawn from within the liner. This arrangement allows the use of inexpensive liners with large interior volumes, without having to resort to complex tubing arrangements to equalize pressure. A sterilizable polymer receptacle is also provided which can withstand the large pressure forces associated with large fluid collection volumes.

In a first aspect, the present invention provides a surgical fluid collector comprising at least one container. Each container includes a receptacle having a rigid receptacle body and a lid. The receptacle body has an open end, over which the lid is sealable to define a vacuum chamber. A liner is disposable within the vacuum chamber of the receptacle, and defines a liner interior. Vacuum and fluid inflow ports are in fluid connection with the interior of the liner through the rigid receptacle. A valve is disposed between the interior of the liner and the vacuum chamber surrounding the liner. The valve allows flow into the interior of the liner, but prevents surgical fluid from flowing from the interior of the liner to the surrounding vacuum chamber. The valve thereby equalizes pressure across the liner material when a vacuum is drawn.

through the vacuum port, the valve typically comprising a simple, low cost, and reliable one-way valve.

In another aspect, the present invention provides a surgical fluid collection system comprising a plurality of 5 containers. Each container comprises a receptacle which defines a vacuum chamber. A liner is disposable within the vacuum chamber of the receptacle, and defines a liner interior. Vacuum and fluid inflow ports are in fluid communication with the interior of the liner through the receptacle. A surgical fluid inflow tube is coupleable to the inflow valve of a first container to drain surgical fluids from a patient body. An intercontainer tube couples the fluid port of a second container with the vacuum port of the first container. Hence, the surgical fluids flow through the liner 10 of the first container and into the liner of the second container when the liner of the first container is full. In 15 most embodiments, each liner holds at least five liters of surgical fluid, and the liners have a combined capacity of at least 20 liters of surgical fluid.

20 In another aspect, the present invention provides a rigid receptacle for use with a disposable surgical fluid collector liner. The liner defines a liner interior, and has a valve which allows flow into the interior of the liner, but which prevents surgical fluid from flowing out from the 25 interior of the liner. The receptacle comprises a rigid polymer body having an open end. A lid is sealable over the open end of the body to define a vacuum chamber. The vacuum chamber has a volume of at least five liters. First and second passages extend through either the lid or the body to 30 provide fluid communication to the interior of the liner.

35 In yet another aspect, the present invention provides a disposable surgical fluid collector liner for use with a rigid receptacle. The receptacle defines a vacuum chamber, and has first and second passages into the vacuum chamber. The liner comprises a flexible pouch bordering an interior of the liner. A vacuum port is in fluid communication with the interior of the liner through the first passage of the receptacle, while a fluid inflow port is

similarly in fluid communication with the interior of the liner through the second passage. A valve is disposable between the interior of the liner and the vacuum chamber surrounding the liner. The valve allows flow into the 5 interior of the liner, but prevents surgical fluid from flowing from within the liner to the surrounding vacuum chamber.

In a method according to the present invention, a vacuum is drawn within a flexible liner while the liner is 10 disposed within a rigid vacuum chamber by coupling a vacuum source to an interior of the liner. The vacuum is distributed within the vacuum chamber surrounding the liner by a one-way valve. Surgical fluids are aspirated from a patient body and into the liner with the vacuum, and the one-way valve prevents 15 the surgical fluids from spilling out of the liner to the surrounding vacuum chamber.

BRIEF DESCRIPTION OF THE DRAWINGS

20 Fig. 1 illustrates a system and method for collecting surgical fluids according to the principles of the present invention.

Fig. 2 illustrates a disposable surgical fluid container liner, for use in the system of Fig. 1.

25 Fig. 3 is an exploded view of a rigid polymer receptacle for use in the system of Fig. 1.

Fig. 4 is a cross-sectional view of a surgical fluid container in which the liner of Fig. 2 is removably disposed within the rigid receptacle of Fig. 3, as used in the system 30 of Fig. 1.

35 Figs. 5A and 5B are perspective views of an alternative receptacle and liner, in which a gasket on the rim of the liner helps seal between the receptacle lid and body, and in which pinch valves on flexible tubing can seal the surgical fluid within the liner.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention allows the collection of surgical fluids into large fluid reservoirs which are connected in a simple series arrangement. This simplified arrangement facilitates the setting-up and breaking-down of the fluid collection system, and also enhances the ease and safety of transporting and disposing of the collected surgical fluids. Hence, the present invention will find applications in a wide variety of medical procedures, including both 5 minimally invasive and open surgical therapies, postoperative care, and the like. The surgical fluid containers, systems, and methods of the present invention will find their most 10 immediate application in minimally invasive surgeries of the thorax, pelvic region, and joints, particularly when such 15 minimally invasive surgeries are performed at an internal surgical site flooded with saline, sorbitol, mannitol, sorbitol-mannitol, or any other conductive or nonconductive fluid medium. The present invention is particularly well suited for use in resection and/or ablation of the endometrial 20 lining of the uterus.

Referring now to Fig. 1, a surgical fluid collection system 10 includes four surgical fluid containers 12 coupled together in series. Each container 12 has a pair of ports 14. Tubing 16 couples containers 12 each other, to a vacuum source 25 18, and to a source of surgical fluids from a patient 20. For example, tubing 16 may couple containers 12 to an endometrial resection probe such as that described in copending U.S. Patent Application Serial No. 08/542,289, filed October 12, 1995 (Attorney Docket No. 16944-000130), the 30 disclosure of which is incorporated herein by reference.

The combined volume of containers 12 will generally have a capacity of at least about 10 liters, preferably being more than about 20 liters to accommodate the large amounts of surgical fluids used in some of the recently developed 35 minimally invasive surgical procedures. To accommodate such large quantities of fluid, each container 12 will preferably have a capacity of greater than about 5 liters, ideally having a capacity of about 8 liters. This gives fluid collection

system 10 a total capacity of about 32 liters with four containers. This total fluid capacity can easily be varied by coupling additional containers 12 in system 10. Generally, between three and seven containers will be included to avoid 5 the complexity of larger numbers of containers and intercontainer connector tubes, and also to limit the weight of each full container for ease of handling and disposal.

In each of containers 12, one of ports 14 acts as a fluid inflow port 22, through which the surgical fluid from 10 patient 20 enters the container. Similarly, the other port 14 acts as a vacuum port 24 through which vacuum source 18 draws down the internal pressure within the container. Once the container has reached its predetermined capacity, surgical fluids which enter inflow port 22 will pass through container 15 12 and out vacuum port 24 for storage within another of the containers.

The use of a single port for application of a vacuum, and also for transferring overflow surgical fluids to an adjacent container, allows the operation of surgical fluid 20 collection system 10 with only two ports per container. This simple serial or "daisy-chain" connection allows the surgical staff to vary the capacity of fluid collection system 10 by simply increasing or decreasing the number of containers 12 which are connected in line between patient 20 and vacuum 25 source 18. Additionally, the lack of any branching interconnections along tubing 16 minimizes residue and simplifies postoperative cleanup. Allowing air to enter the system after the fluid has been collected may help to clear any residual surgical fluids from the tubing and distribute it 30 entirely within containers 12, thereby minimizing the likelihood of any significant spillage while separating the elements of collection system 10.

Referring now to Figs. 2-4, each container 12 35 generally comprises a disposable liner 26 and a rigid receptacle 28. Liner 26 includes a flexible polymeric pouch 30 which is sealed about the lower perimeter of a semi-rigid or rigid lid 32. Lid 32 supports a one-way valve 34, a

sealable cap 36, and a pair of knock-down valves 38. A rim 40 extends radially from lid 32, and a significant portion of the rim is separated from the lid by a circumferential slot 42.

5 Surgical fluids 44 (see Fig. 4) are contained within an interior 46 of liner 26. Liner interior 46 is sealed by the surrounding flexible pouch 30 and lid 32, with the exception of break-down valves 38, cap 36, and one-way valve 34. Flexible pouch 30 typically comprises a polymer such as polyvinyl chloride (PVC), but may be formed of a wide 10 variety of alternative materials. Similarly, lid 32 ideally comprises acrylic butadiene styrene (ABS), but may alternatively be formed from a variety of materials. Lid 32 will generally have sufficient strength to substantially maintain its shape while supporting the weight of surgical 15 fluid 44, so as to facilitate removal of disposable liner 26 from receptacle 28.

One-way valve 34 is arranged to allow flow from outside liner 26 to the liner interior 46, but to block flow from the interior of the liner to the surrounding environment. 20 Thus, one-way valve 34 prevents the release of surgical fluids from liner interior 46 once the liner is full. One-way valve 34 preferably comprises a simple diaphragm flapper valve such as that available commercially from Qosina of Edgewood, New York, under Model No. 51465. Sealable cap 36 allows access to 25 the collected surgical fluid 44 for inspection and/or testing prior to disposal of the filled liner 26. Knock-down valves 38 are rotatably mounted to lid 32, and seal ports 14 from liner interior 46 when tubular bodies 48 are oriented horizontally. To open knock-down valves 38 and allow access 30 through ports 14, tubular bodies 48 are simply oriented upward.

As can be understood most clearly with reference to Figs. 3 and 4, rigid receptacle 28 generally comprises a receptacle body 50 and a receptacle lid 52. Receptacle body 35 50 and receptacle lid 52 define a vacuum chamber 53, and should ideally have sufficient strength and structural rigidity to withstand an external load of 1 atmosphere. To facilitate sterilization, minimize weight, and withstand the

substantial pressure loads associated with the large volumes of surgical fluid of the n w minimally invasive surgical procedures, receptacle body 50 and receptacle lid 52 are preferably formed of a high strength, high temperature 5 polymer, such as Ultem® from General Electric. A handle 54 allows receptacle 28 to hang from an I.V. stand or the like. O-rings 56 are inset within grooves of the receptacle body 50 and receptacle lid 52, and the lid is clamped on to the body using clips 58. Alternatively, a gasket attached to liner rim 10 40 may allow sealing without O-rings.

Receptacle lid 52 includes two through holes 60 through which knockdown valves 38 protrude when tubular bodies 48 are vertically oriented. Tubing bodies 48 have compliant rings 49 which seal against the lid material bordering holes 15 60. Protrusions 62 along rim 40 mate with detents in the receptacle lid to help align knock-down valves 38 with inserts 60.

Rim 40 of disposable liner 26 helps to seal receptacle 28, and also provides a handle which facilitates 20 removal and disposal of the surgical fluids. Rim 40 is disposable between the O-rings 56 of receptacle lid 52 and receptacle body 50. As mentioned above, a gasket on rim 40 may provide sealing without O-rings. Once the disposable 25 liner is full, the portion of rim 40 which is separated from lid 32 by slot 42 can be flexed upward away from the receptacle body. By flexing the two opposed portions of rim 40 upward and together, they define a convenient carrying handle 63 for removing and carrying the filled disposable pouch. As lid 32 substantially separates vacuum chamber 53 30 into an upper chamber 64 and a lower chamber 66, slots 42 also allow the pressure to equalize between these volumes, thereby avoiding the imposition of large pressure forces against the lid of the disposable liner.

In use, a member of the surgical team will determine 35 the surgical fluid capacity required for a particular procedure, and will provide at least enough containers 12 to accommodate that predetermined fluid volume. A disposable liner 26 is placed in each receptacle body 50 with rim 40

engaging the associated O-ring 56. Optionally, protrusions on the bottom of rim 42 (similar to protrusions 62 on top of the rim) engage associated detents in the receptacle body (not shown). Tubular bodies 48 of knock-down valves 38 are oriented upward to open the valves, and to provide access to the interior of the liner through ports 14. Receptacle lid 52 is positioned over the receptacle body by sliding tubular bodies 48 through holes 60, and also by aligning protrusions 62 with associated detents in the bottom of the receptacle lid (not shown). O-ring 56 associated with receptacle lid 52 engages the top of rim 40 of disposable liner 26, so that the rim is sandwiched between the two O-rings. As tubular bodies 48 seal in holes 60, the only openings through receptacle 28 are ports 14, which are in communication with the interior of the liner.

As can be understood with reference to Fig. 1, tubing 16 couples a first of the containers with the source of surgical fluids within patient 20. This leaves only one open passage through the receptacle of the first container. In the exemplary embodiment, the two ports are identical, so that either port 14 can be used as fluid input port 22. The remaining port is then coupled to either of the two ports of an adjacent container 12, and through that container, on to the vacuum. As each container 12 has only two ports, and as they are interchangeable, there is little likelihood that fluid containment system 10 will be coupled together improperly.

The remaining containers are coupled to the vacuum ports of a preceding container until there are sufficient containers coupled together to accommodate the predetermined volume of surgical fluid. The final container is then coupled by tubing 16 to vacuum source 18. It should be understood that there may be valves, filters, pressure regulators, and the like disposed between containers 12 and vacuum source 18, and optionally between patient 20 and containers 12.

As can be understood with reference to Figs. 1 and 4, vacuum source 18 draws down the pressure within each container 12 by withdrawing air and/or fluids through vacuum

port 24. Pressure in interior 46 of liner 26 is equalized with the surrounding vacuum chamber 53 by air flowing through one-way valve 34 from around the liner, as shown in Fig. 4. Grooves or ridges within receptacle body 50 may help prevent 5 flexible pouch 30 of liner 26 from sealing against the surrounding receptacle body, enhancing the distribution and equalization of pressure throughout the vacuum chamber (not shown). Air also flows from below lid 32 into upper chamber 64 through slots 42, which are shown most clearly in Fig. 2. 10 Thus, pressure loads on both the flexible liner pouch and the liner lid are substantially avoided.

Fluid initially flows from patient 20 to the first container 12, where it is contained within the interior of the liner. As fluid 44 fills interior 46 of liner 26, one-way 15 valve 34 equalizes pressure within liner interior 46 and surrounding the liner within vacuum chamber 53. However, once fluid 44 substantially fills liner interior 46, one-way valve 34 prevents the fluid from spilling out of the liner to the surrounding vacuum chamber. Additional fluid then begins to 20 flow out through vacuum port 24.

Any additional fluid will then flow through the interior of the liner of the first container, and then on through tubing 16 to the inflow port 22 of the adjacent container 12. That adjacent container will then begin to 25 fill, and if sufficient fluid is introduced from patient 20 to fill the second container, the overflow will again proceed on to the next container, and so on. The introduction of fluid will preferably cease before the final container is completely full.

30 Once fluid collection system 10 is full, or once the surgical procedure has ended, tubing 16 is detached from containers 12, and clips 58 are opened to allow receptacle lid 52 to be removed. Tubular bodies 48 of knock-down valves 38 are placed in a horizontal position, sealing fluid 44 within 35 the interior 46 of liner 26.

By grasping rim 40 along slot 42, the rim can be flexed upward away from receptacle body 50. Thus, the rim forms a convenient handle for lifting the filled disposable

liner 26 from the receptacle body, and for carrying surgical fluid 44 to a disposal site. One-way valve 34, sealable cap 36, and knock-down valves 38 prevent the leakage of surgical fluid 44, even if the liner is inadvertently dropped during 5 transportation. Access to surgical fluid 44 may be provided by actuating one of the knock-down valves, or through sealable cap 36.

An alternative receptacle 70 and a corresponding liner 72 are illustrated in Figs. 5A and 5B, respectively. 10 Rim 40 is here provided with a gasket 74 to effect sealing between body 76 and lid 78. Gasket 74 extends onto the upper and lower surfaces of rim 40 to seal directly against the material of lid 78 and body 76, so that no O-rings are required. Ridges 80 reinforce body 76, and also distribute 15 and equalize pressure around the liner.

Liner 72 includes flexible tubing 82 between angled fittings 84 and fixed tubular bodies 86. Pinch clamps 88 on tubing 82 seal the collected surgical fluids within the liner.

While the exemplary embodiments have been described 20 in some detail, by way of example and for clarity of understanding, a variety of changes, modifications, and adaptations of the present invention will be obvious to those of skill in the art. For example, flexible tubes may couple the interior of the liner to fluid inflow and vacuum ports 25 affixed to the receptacle. Thus, the scope of the present invention is limited solely by the appended claims.

WHAT IS CLAIMED IS:

1        1. A surgical fluid collector comprising at least  
2        on container, each container including:  
3                a receptacle having a rigid receptacle body and a  
4                lid, the receptacle body having an open end, the lid sealable  
5                over the open end to define a vacuum chamber;  
6                a liner disposable within the vacuum chamber of the  
7                receptacle, the liner defining a liner interior;  
8                a vacuum port in fluid communication with the  
9                interior of the liner through the rigid receptacle;  
10               a fluid inflow port in fluid communication with the  
11               interior of the liner through the rigid receptacle; and  
12               a valve disposed between the interior of the liner  
13               and the vacuum chamber surrounding the liner, the valve  
14               allowing flow into the interior of the liner and preventing  
15               surgical fluid from flowing from the interior of the liner to  
16               the surrounding vacuum chamber.

1        2. A collector as claimed in claim 1, wherein the  
2        valve comprises a one-way valve.

1        3. A collector as claimed in claim 2, wherein the  
2        liner comprises a flexible pouch and a lid which is more rigid  
3        than the liner pouch, the one way valve being mounted to the  
4        liner lid, and further comprising a rim extending radially  
5        from the liner lid, the rim being disposable between the  
6        receptacle body and the receptacle lid to help seal the vacuum  
7        chamber, the liner lid and rim substantially separating the  
8        vacuum chamber into an upper portion and a lower portion, an  
9        opening being disposed between the rim and the liner lid to  
10       equalize pressure between the upper portion and the lower  
11       portion of the vacuum chamber.

1        4. A collector as claimed in claim 3, wherein the  
2        opening comprises at least one slot which separates a portion  
3        of the rim from the adjacent liner lid, the portion of the rim  
4        defining a handle which is movable away from the liner lid to  
5        facilitate lifting the liner from the body of the receptacle.

1               5. A collector as claimed in claim 2, further  
2 comprising first and second tubular bodies which are  
3 extendable from the liner through the receptacle to the vacuum  
4 port and the fluid port, respectively, the receptacle being  
5 sealed about the tubular bodies.

1               6. A collector as claimed in claim 5, further  
2 comprising a shut-off valve disposed along each tubular body  
3 to seal the interior of the liner.

1               7. A collector as claimed in claim 1, wherein the  
2 liner holds at least 5 liters of surgical fluid.

1               8. A collector as claimed in claim 1, further  
2 comprising a plurality of containers, the fluid port of the  
3 first container being coupleable to a source of surgical  
4 fluids from a patient body, the fluid port of a second  
5 container being in fluid communication with the vacuum port of  
6 the first container so that the surgical fluid flows through  
7 the liner of the first container and into the liner of the  
8 second container when the liner of the first container is  
9 full.

1               9. A collector as claimed in claim 8, wherein the  
2 vacuum port and the fluid port of each container are  
3 interchangeable.

1               10. A collector as claimed in claim 8, wherein 3 or  
2 more containers are coupled in series, and wherein the liners  
3 have a combined capacity of at least 20 liters of surgical  
4 fluid.

1               11. A collector as claimed in claim 1, wherein the  
2 fluid port and the vacuum port are coupled to the interior of  
3 the liner through first and second tubular bodies, and wherein  
4 the receptacle seals around the tubular bodies so that the

5 container is adapted to collect surgical fluid in the liner  
6 when the tubular bodies are the only open passages through the  
7 receptacle.

1 12. A surgical fluid collection system comprising:  
2 a plurality of containers, each container  
3 comprising:

4 a rigid receptacle which defines a vacuum  
5 chamber;

6 a liner disposable within the vacuum  
7 chamber of the receptacle, the liner defining a liner  
8 interior;

9 a vacuum port in fluid communication with  
10 the interior of the liner through the receptacle; and

11 a fluid inflow port in fluid communication  
12 with the interior of the liner through the receptacle;

13 a surgical fluid inflow tube coupleable to the  
14 inflow valve of a first container to drain surgical fluids  
15 from a patient body; and

16 an inter-container tube for coupling the fluid port  
17 of a second container with the vacuum port of the first  
18 container so that the surgical fluids flow through the liner  
19 of the first container and into the liner of the second  
20 container when the liner of the first container is full.

1 13. A system as claimed in claim 12, wherein each  
2 liner holds at least 5 liters of surgical fluid, and wherein  
3 the liners have a combined capacity of at least 10 liters of  
4 surgical fluid.

1 14. A rigid receptacle for use with a disposable  
2 surgical fluid collector liner, the liner defining a liner  
3 interior and having a valve which allows flow into the  
4 interior of the liner and prevents surgical fluid from flowing  
5 from the interior of the liner, the receptacle comprising:

6           a rigid polymer body having an open end;  
7           a lid sealable over the open end of the body to  
8 define a vacuum chamber, the vacuum chamber having a volume of  
9 at least 5 liters;  
10           first and second passages through a structure  
11 selected from the group comprising the body and the lid to  
12 provide fluid communication to the interior of the liner.

1           15. A disposable surgical fluid collector liner for  
2 use with a rigid receptacle which defines a vacuum chamber,  
3 the receptacle having first and second passages into the  
4 vacuum chamber, the liner comprising:

5           a flexible pouch bordering an interior of the liner;  
6           a vacuum port in fluid communication with the  
7 interior of the liner through the first passage of the  
8 receptacle;

9           a fluid inflow port in fluid communication with the  
10 interior of the liner through the second passage of the  
11 receptacle; and

12           a valve disposable between the interior of the liner  
13 and the vacuum chamber surrounding the liner, the valve  
14 allowing flow into the interior of the liner and preventing  
15 surgical fluid from flowing from the interior of the liner to  
16 the surrounding vacuum chamber.

1           16. A method for collecting surgical fluid, the  
2 method comprising:

3           drawing a vacuum within a flexible liner while the  
4 liner is disposed within a rigid vacuum chamber by coupling a  
5 vacuum source to an interior of the liner;

6           distributing the vacuum within the vacuum chamber  
7 surrounding the liner with a one-way valve;

8           aspirating surgical fluid from a patient body and  
9 into the liner with the vacuum; and

10           preventing the surgical fluid from spilling out of  
11 the liner and into the vacuum chamber surrounding the liner  
12 with the one-way valve.

1           17. A method as claimed in claim 16, further  
2   comprising drawing the surgical fluid through the interior of  
3   the first liner and into another vacuum chamber with the  
4   vacuum source when the first liner is full.

1           18. A method as claimed in claim 15, further  
2   comprising sealing a lid of the chamber to a body of the  
3   chamber with a rim affixed to the liner, and removing the  
4   liner from the chamber by grasping the rim along an opening  
5   between the rim and the liner.

1/3

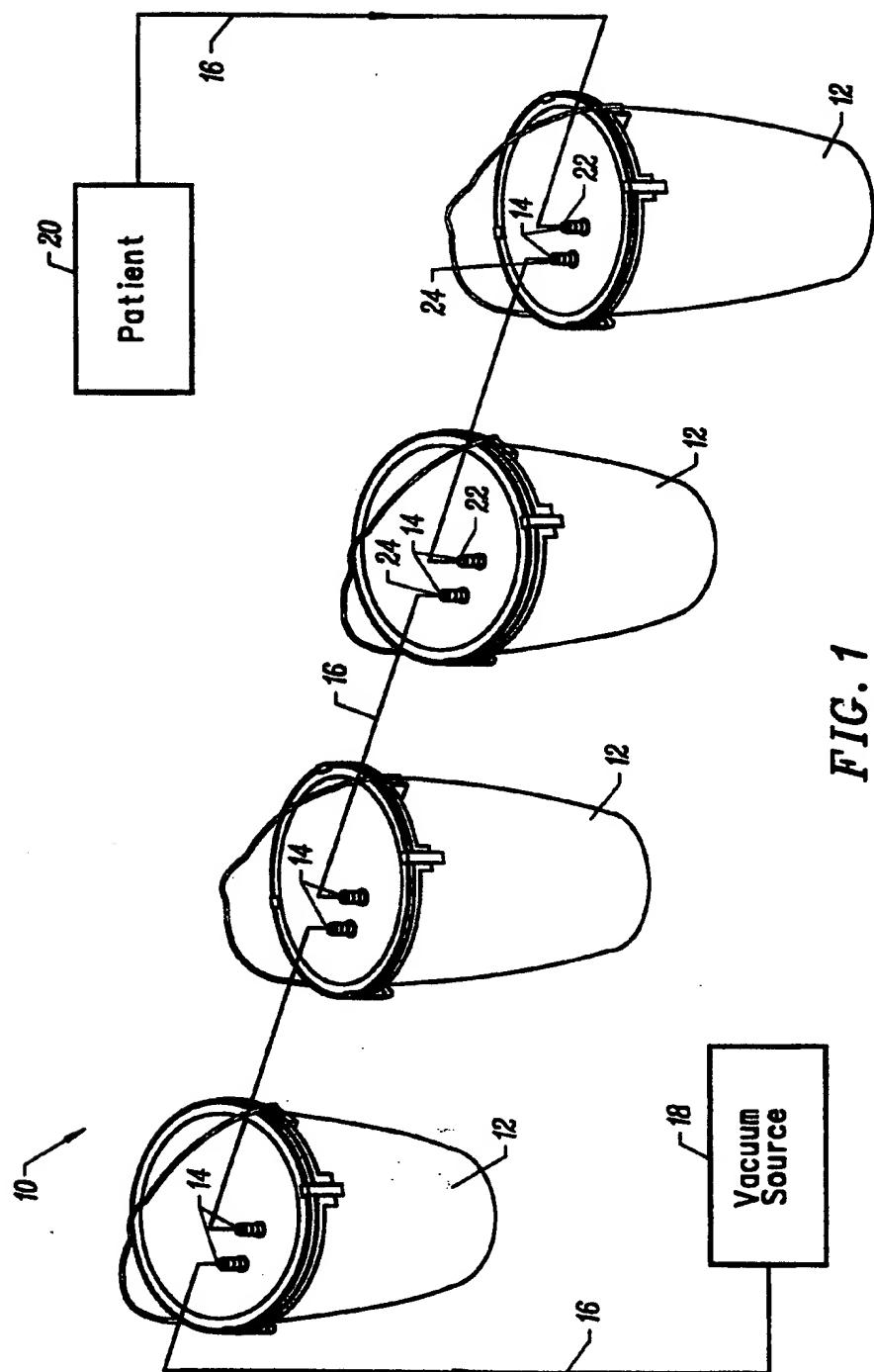


FIG. 1

2/3

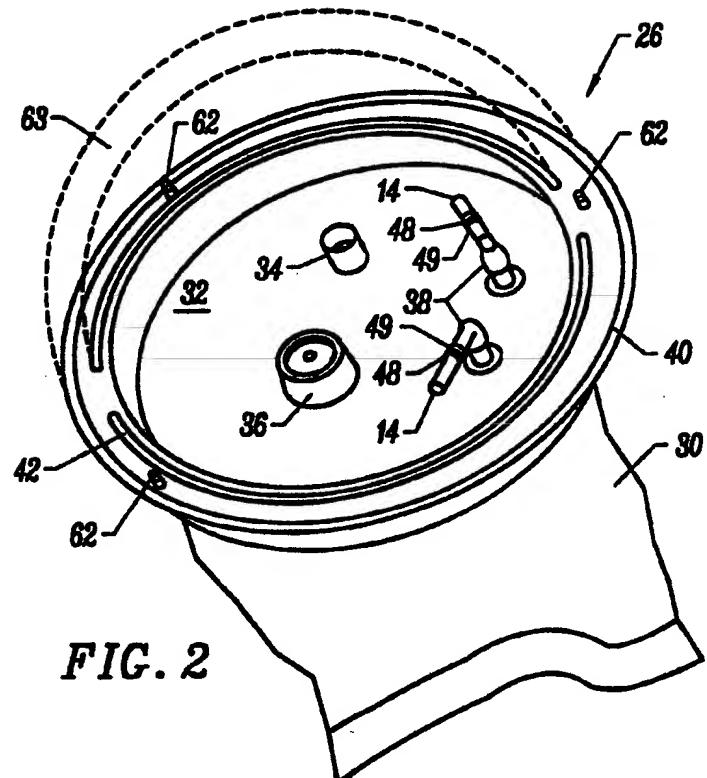


FIG. 2

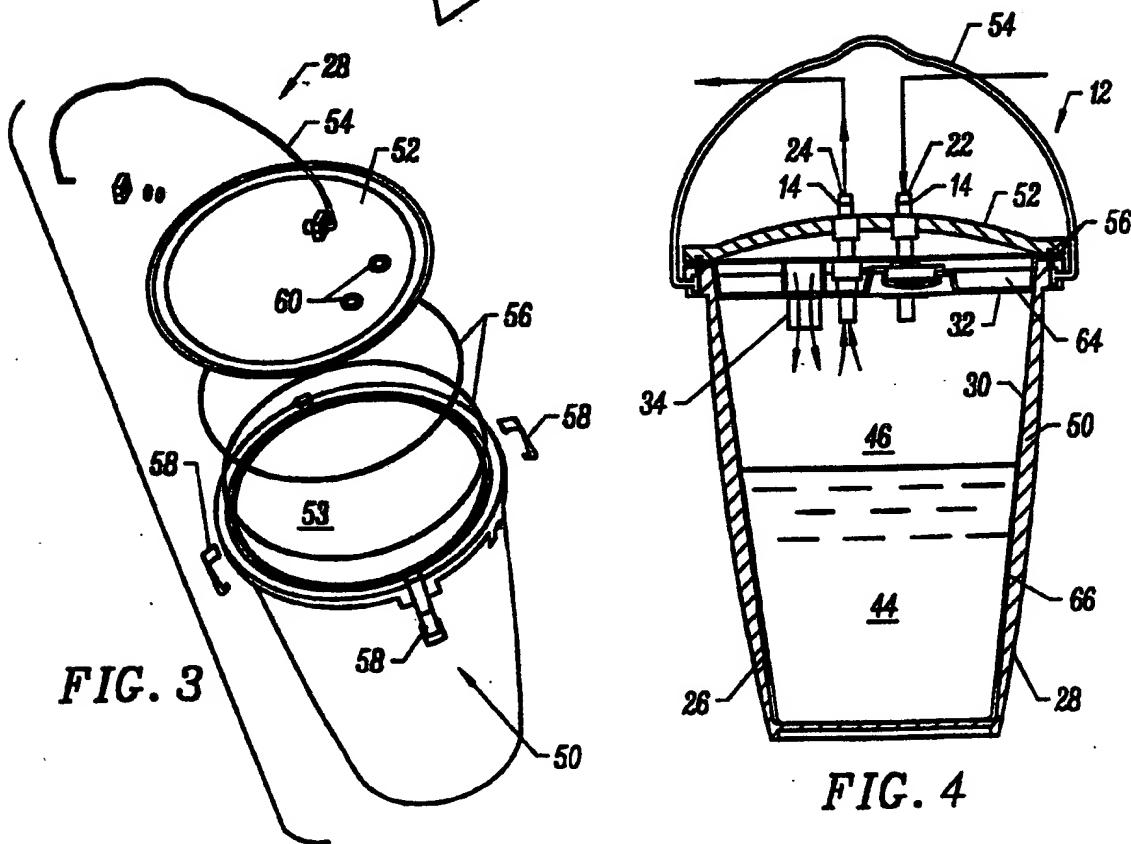


FIG. 3

FIG. 4

3/3

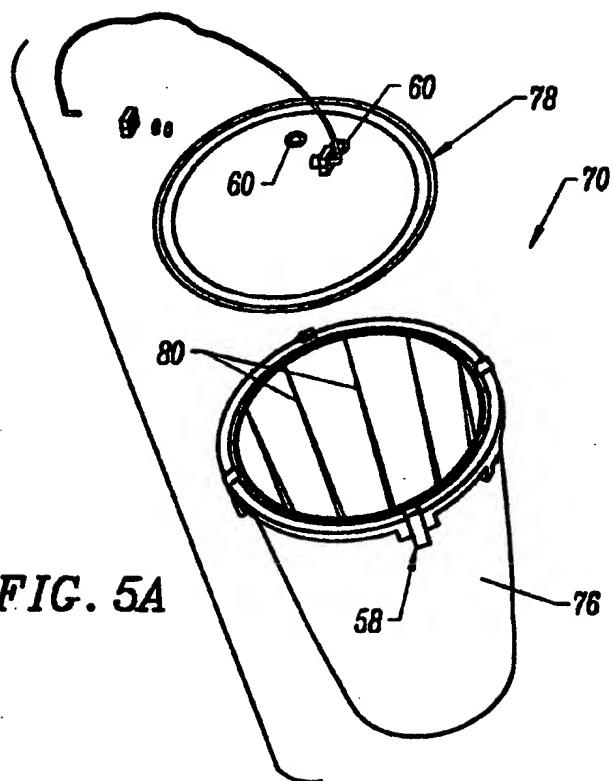


FIG. 5A

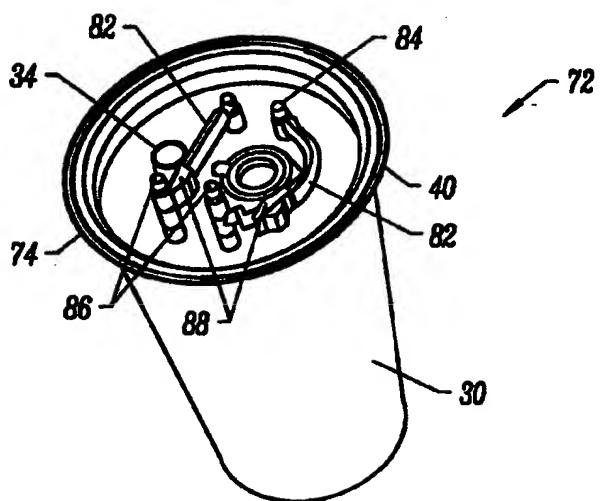


FIG. 5B

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/11239

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 1/00  
 US CL : 604/317, 319-323

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/317, 319, 320, 321, 322, 323, 403, 408; 128/760; 137/205; 141/59

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,384,580 A (LEVITON) 24 May 1983, entire document.	1-18
X	US 4,388,922 A (TELANG) 21 June 1983, entire document.	1-18
X	US 4,460,361 A (NICHOLS) 17 July 1984, Abstract, and figures.	1
Y	US 4,321,922 A (DEATON) 30 March 1982, Abstract, and figures.	1

Further documents are listed in the continuation of Box C.  See patent family annex.

Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance		
"E" earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"A"	document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

24 AUGUST 1998

Date of mailing of the international search report

28 SEP 1998

Name and mailing address of the ISA/US  
 Commissioner of Patents and Trademarks  
 Box PCT  
 Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

DAVID J. CHO

Telephone No. (703) 308-0073